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DIVISION OF PROFESSIONAL REGULATION

PUBLIC MEETING NOTICE:	CONTROLLED SUBSTANCE COMMITTEE
DATE AND TIME:	Wednesday, December 1 at 9:00 a.m.
PLACE:	Buena Vista, Second Floor Conference Room, 661 S. DuPont Highway, New Castle, Delaware 19720
APPROVED:	

MEMBERS PRESENT

Michael Kremer, DMD, Dental Representative, President
Luis Garcia, Jr., DPM, Podiatric Representative, Vice President
Robert Flanagan, DVM, Vet Representative
Mark Hanna, Public Representative
Howard Simon, R.Ph, Pharmacy Representative
Bonnie Wallner, R.Ph., Pharmacy Representative
Stephen Ruggles, PA-C, PA Representative
David W. Dryden, R.Ph., J.D., Director Office of Controlled Substances

MEMBERS ABSENT

Philip Kim, M.D., Medical Representative
Ann Dominick, APN, Nursing Representative

DIVISION STAFF/DEPUTY ATTORNEY GENERAL

Judy Letterman, Administrative Specialist

ALSO PRESENT

Jean Chiquoine
Cheryl Heiks
Bruce Divincenzo
Caryn Tazartus

CALL TO ORDER

Dr. Kremer called the meeting to order at 9:05 a.m.

REVIEW AND APPROVAL OF MINUTES

A motion was made by Mr. Garcia, seconded by Mr. Hanna, to accept the minutes as amended. The motion was unanimously carried.

PRESIDENT'S REPORT

Dr. Kremer informed the Committee that there was nothing new to report other than the two hearings which are continued. Mr. Dryden informed the Committee that Thomas Ceello surrendered his license.

UNFINISHED BUSINESS

Security Updates

Mr. Dryden presented a handout of security requirements approved by the Committee at the previous meeting. The standards include but are not limited to the implementation of a floor to ceiling physical barrier limiting access to the pharmacy area, motion detectors, strategically placed surveillance cameras and back-up alarm systems. He reviewed a few scenarios of pharmacy security issues which arose in the last quarter. The Committee still agrees with these security requirements as described and would like to see these standards in the Regulation.

NEW BUSINESS

Registrant Application Reviews

There were no applications that required review.

DIRECTORS REPORT

Staffing

Mr. Dryden introduced Alicia Kluger as the new Pharmacist Compliance Officer for the Division. Ms. Letterman will be the Administrative Specialist who will assist with the Controlled Substance Committee, Board of Pharmacy and National reporting efforts.

Panel Hearing Schedules

Mr. Dryden provided the Committee with a handout of the panel hearing schedule. Members should report any concerns with attending these dates as soon as possible. These are tentative dates for emergency suspension hearings which will probably not be required but will be scheduled in advance for efficiency and to provide timely hearings for registrants.

Case/Diversion Review

Mr. Dryden reviewed controlled substance actions on registrant registrations.

Prescription Monitoring Program (PMP) Review

Mr. Dryden reported he had attended the Alliance PMP meeting held in Charleston, South Carolina. The meeting was very PMP educational and a number of contacts were made. The Division continues to search for monies to fund the PMP. The Office of Controlled Substances is working on the RFP and will be requesting aid from the Controlled Substance Regulatory Committee at a future time.

National Association of State Controlled Substance Authorities (NASCSA) Review

Mr. Dryden reported he attended the NASCSA meeting also held in Charleston, South Carolina. This meeting was very controlled substance educational.

Controlled Substance E-Prescribing

Mr. Dryden provided a handout of e-prescribing information that has been drafted explaining the controlled substance e-prescribing status. Effective June 1, 2010 the electronic transmission of controlled substances was approved. As an overview, practitioners have the option of signing and transmitting prescriptions for controlled substances electronically. Pharmacies are permitted to receive, dispense and archive electronic prescriptions of schedule II-V controlled

substances. Pharmacies may only process electronic controlled substance prescriptions using applications determined to meet DEA's requirements. Every practitioner and every pharmacy will need to meet DEA requirements. Each practitioner and pharmacy will need to be independently audited by a DEA approved auditor. Software will need to be developed for practitioners and pharmacies. Prescribing practitioners must undergo identity proofing. Remote identity proofing is permissible. Institutional practitioners may use different methods specific to their needs. After identity is verified the practitioner will be issued a two factor authentication credential. Prescriptions must be transmitted as soon as possible after signature. Prescriptions must remain in an electronic condition; conversion to fax is not permitted. Prescriptions may be printed after signature so long as they are labeled "copy only – not valid for dispensing". Pharmacy records must be backed up daily, should be retrieved via practitioner name, patient name, drug name, and date dispensed and should be maintained for at least two years.

Actual electronic transmissions of controlled substance prescriptions are not expected by federal authorities to occur until the summer of 2011.

Whenever our Office receives updated information, we will provide this information via our web site.

Committee members were encouraged to forward any inquiries of controlled substance e-prescribing to the Office of Controlled Substances or the Division's web site.

Current Event Review

Mr. Dryden provided a handout of the following topics of current events:

- *DEA National Disposal Event*
- *Secure and Responsible Drug Disposal Act*
- *FDA Advisory Committee Votes Not to Schedule Dextromethorphan*
- *Substance Abuse Stats*
- *Methamphetamine Enhancement Act*
- *Xanodyne agrees to withdraw propoxyphene from the U.S. market*
- *DEA allows nurses to relay pain medication prescriptions to pharmacies*
- *FDA, Other Regulators Coordinate Actions to Fight Internet Drug Outlets*
- *New Tamper-Resistant OxyContin Tablets to be Released August 2010*
- *Stolen Carbatrol and Adderall XR Found in Supply Chain*
- *Canadian Man Sentenced In US Court for Selling Counterfeit Cancer Drugs Over Internet*

COMMITTEE REPORTS

Medical Examiner's Report

Caryn Tazartus provided pictures and informed the Committee of a new candy containing cannabis obtained through a State Police drug bust.

DEA Report – Philip Reed

No Report.

Substance Abuse Report

No report.

Law Enforcement Report

Chief Agent DiVincenzo reported that their office has been very active in investigating controlled substance diversion. He also stated that there was a proposed federal law concerning spice synthetic marijuana.

Regulatory Committee

Mr. Dryden provided a handout of draft amended controlled substance regulations from Ms. Davis-Oliva. Mr. Dryden will be meeting with Ms. Davis-Oliva to review the edits made. A Controlled Substance Regulatory Committee meeting will be scheduled after a draft is ready for their further review.

Legislative Committee

Mr. Dryden provided a handout pertaining to K2 and federal emergency plans to provide law that will cover this issue. Mr. Dryden will contact the DEA for further information regarding these plans.

INSPECTION REPORT

Ms. Kluger stated that she was in the training process for inspections of controlled substance registrants.

COMMITTEE CORRESPONDENCE

None

OTHER BUSINESS BEFORE THE BOARD

The division calendar will be updated with the dates, place and time of the meetings.

PUBLIC COMMENT

No public comment

EXECUTIVE SESSION

The Committee went into Executive Session at 10:05 a.m.

After the Committee discussion, a motion was made by Mr. Kremer, seconded by Mr. Garcia to close executive session. The motion was unanimously carried.

NEXT SCHEDULED MEETING

The next meeting will be held on Wednesday, February 23, 2011 at 9:00 a.m.

Adjournment

A motion was made by Dr. Kremer, seconded by Mr. Hanna, to adjourn the meeting. The motion unanimously carried. The meeting adjourned at 10:10 a.m.

Respectfully submitted,

David W. Dryden, R.Ph., Esq.